

REMARKS

Claims 25, 26, 27-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 94, 95-97, 101, 103, 105, 108 and 109 are pending. By this amendment claims 25, 27, 52, 54, and 83 have been amended, and new claims 108 and 109 have been added. Claims 27 and 54 have been placed in independent form. Support for the amendments to the claims is provided, for example, by the paragraph bridging pages 12 and 13 and by claims 25 and 52. Support for new claims 108 and 109 is provided, for example, by the paragraph bridging pages 11 and 12, Table 2 on page 42, and by claim 52. No new matter has been introduced.

In the Disposition of Claims section of the Office Action, Claims 26, 27, 50, 54, and 94 are omitted. Claims 26, 50, and 94 were withdrawn from consideration but claims 27 and 54 were not withdrawn in the previous Office Action of June 15, 2006. However, claims 27 and 54 are rejected in the present Office Action. Thus, although not indicated in the Disposition of Claims, or anywhere else in the Office Action, it appears that claims 26, 50, and 94 stand withdrawn because they are not mentioned in any of the rejections. Clarification of the status of Claims 26, 50, and 94 is courteously requested. Claims 1-24, 32-33, 36, 41, 43-45, 47-49, 51, 60, 63, 68, 71-72, 74, 76-78, 80, 86-90, 98-100, 102, 104, and 106-107 have been canceled. Pending Claims 25, 27-31, 34-35, 37-40, 42, 46, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, and 105 are rejected in the present Office Action.

In the September 16, 2004 Ex Parte Quayle Action, the elected species indicated as allowable were: (1) durum wheat as the plasticized matrix material and (2) a probiotic nutraceutical component as an encapsulant. Applicant notes that the election of species requirement directed to the rate-controlling agent (hydrophobic component/fat) was withdrawn in the Office Action dated March 17, 2003. As to the additional matrix material, Applicant elected starch as the additional matrix material in Claim 79. As to the encapsulant form, Applicant elected the liquid encapsulant of Claim 93. In the December

13, 2005 Office Action, the Examiner chose plasticized starch as the next species for the plasticized matrix material for examination.

The elected species of durum wheat as a plasticized matrix material was therefore indicated as allowable because the Examiner chose plasticized starch as the next species of plasticized matrix material to be examined. See the paragraph bridging pages 4 and 5 of the June 16, 2006 Final Rejection. Thus, with respect to the originally elected species of durum wheat as a plasticized matrix material, claims readable thereon and which should be indicated as allowable with respect to durum wheat as the plasticized matrix material are Claims 25, 27-31, 34-35, 37-40, 42, 46, 52, 54-59, 61-62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, and 105. Also, Applicant respectfully asserts that withdrawn Claims 26 and 50, like examined, pending Claim 53, recite plasticized starch as a matrix material and thus should not be indicated as withdrawn, but as pending in view of the Examiner's selection of plasticized starch as the next species for examination. Also, there is no extra burden on the Examiner, because claim 53 has been examined.

It is not clear whether the Examiner has chosen another species of matrix material for examination or whether the examination is on the previously selected species of matrix material (plasticized starch), or whether the election of species requirement has been withdrawn. The rejection under 35 U.S.C. 102(b) mentions that water insoluble polymers of Grabowski et al (U.S. 6,290,990) include polyvinyl pyrrolidone, cross-linked starches, and starch derivatives. In the rejection under 35 U.S.C. 103, the Examiner states that Grabowski et al "does not disclose the compositions comprise semolina in the plasticized matrix" and that Seppala et al (U.S. 6,011,092) discloses thermally plasticized compositions comprising starch.

Clarification regarding the restriction requirement and election of species is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of all previous rejections in response to Applicant's Appeal Brief.

It is believed that the claims reading on the elected species are Claims 25, 27-31, 34-35, 37-40, 42, 46, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, and 105, as well as withdrawn claims 26 and 50, and new claims 108 and 109.

THE REJECTIONS UNDER 35 USC 112, SECOND PARAGRAPH

Claims 25, 27-31, 34, 35, 37, 38, 42, 46, 52-59, 61, 62, 64-67, 69,70, 73, 75, 79, 82, 83, 91-93 and 95-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

The Examiner, citing MPEP 2173.05(b) and *Amgen v. Chugai*, 18 USPQ2d 1016, maintains that the term "at least about" is indefinite because the term "at least" delineates only numerical values more than the recited value where the term "about" may be less than or more than the recited value, and because of the conflict of terms, it is unclear which term is limiting.

However, acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. In determining the range encompassed by the term "about", one must consider the context of the term as it is used in the specification and claims of the application. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326, 81 USPQ2d 1427, 1432 (Fed. Cir. 2007). In *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. However, the court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

The term "at least about" is not inherently indefinite and does not contain conflicting terms. Those skilled in the art would know what is meant by the claim language "about 40% by weight." Even if it delineates a number less than 40% by weight, for example 39% by weight, those skilled in the art would know that the term "at least about 40% by weight" would mean that number or more, for example 39% or more than 39% by weight. There is no conflict seen in the term as alleged by the Examiner. Infringement could clearly be assessed by weighing the final product, and determining or analyzing the weight of the matrix material in the final product. Clear guidance is given in the present specification to those skilled in the art to employ an effective encapsulating amount of matrix material as recited in the present specification at page 12 second full paragraph, and the examples and Table 2 at page 42 give specific ranges for amounts.

The Examiner also maintains that the term "substantially" in claims 25, 37, 52, 64 and 83 is a relative term which renders the claim indefinite. According to the Examiner, the term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. According to the Examiner it cannot be determined what degree is encompassed by "substantially homogeneous," "substantially non-expanded," and "substantially non-cellular structure". However, the term "substantially" is well accepted in the art in conjunction with another term to describe a particular characteristic of the claimed invention. The terms objected to by the Examiner are sufficiently definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). One of ordinary skill in the art would know what was meant by the terms." *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988). The present specification provides clear guidance to those skilled in the art as to mixing and extrusion conditions for obtaining a substantially homogenous mixture and to obtaining a substantially non-expanded, non-cellular structure at, for example, page 22 line 12 to page 27 line3, and page 29 lines 9-13 where exemplary specific densities are provided.

Reconsideration and withdrawal of the rejection is respectfully requested.

THE REJECTION UNDER 35 U.S.C. 102(b)

Claims 25, 28-31, 34, 35, 37-40, 46, 52, 55-59, 61,62, 64-67, 73, 75, 79, 81, 83, 91, 92, 95-97, 101, 103 and 105 are rejected under 35 U.S.C. 102(b) as being anticipated by Grabowski et al. (US 6,290,990). This rejection is respectfully traversed.

Grabowski et al does not teach or suggest the use of a plasticizer comprising water as claimed in independent claims 25, 52, and 53 and their dependent claims.

The Examiner maintains that Grabowski et al. disclose slow-release matrix pellets, where the matrix is plasticized by lipophilic substances and is composed of a polymer which is insoluble in water and gastrointestinal fluids, such as ethyl cellulose, cellulose ethers, insoluble, polysaccharides and microcrystalline cellulose. The Examiner points out that the reference discloses at least one water-insoluble lipophilic component with plasticizer properties for the polymer and lubricant properties include stearic acid, polyethylene oxides, polypropylene oxides and wax. The Examiner also indicates that Grabowski et al discloses the matrix may also comprise at least one natural or semi-synthetic hydrophilic polymer which in water or gastrointestinal fluids forms a highly viscous colloidal solution (hydrocolloid) or at least swells (abbreviated to "gel former"), such as hydroxyalkyl celluloses, alginic acids, gums pectins, and carboxymethyl celluloses, and water insoluble polymers such as polyvinyl pyrrolidone, cross-linked starches and starch derivatives. The composition, as pointed out by the Examiner, includes auxiliaries at concentrations ranging from 0-50% by weight, which may include plasticizers such as polyethylene glycols, polypropylene glycols and glycerol ranging from 0.5 to 15% of the total weight of the pellets.

However, Grabowski et al teaches production of pellets in a one-stage process without previous mixing or pregranulation of the components by melt extrusion of certain polymer matrices which contain active substances. According to Grabowski et al the basic principle of the polymer matrix according to the invention is a matrix which is plasticized

by suitable lipophilic substances and is composed of a polymer which is insoluble in water and gastrointestinal fluids. The gel former, it is disclosed, is included to break up the release-slowing matrix by swelling of this polymer and the active substance can be completely released upon use of the product. See col. 2, line 33 to col. 3 line 8. However, Grabowski does not employ water as a plasticizer for the matrix material and specifically teaches away from its use in producing the product. According to Grabowski et al, "The melt contains no solvent. This means that no water and no organic solvent is added." (Emphasis Added.)

In addition, a rejection under 35 U.S.C. 102(b) is not proper because the September 18, 2001 patent date of Grabowski et al is subsequent to applicant's filing date of May 17, 1999 in parent application U.S. application no. 09/269,763, and subsequent to applicant's October 27, 1997 international filing date of priority International Application No. PCT/US97/18984. While the Grabowski et al patent may be applied as a reference under 35 U.S.C. 102(e), in view of the October 17, 1996 102(e) date and Section 371 date, the reference does not anticipate nor render obvious applicants' claims for reasons as set forth above.

Reconsideration and withdrawal of the rejection is respectfully requested.

THE REJECTIONS UNDER 35 U.S.C. 103(a)

Claims 42, 53, 69, 70 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grabowski et al. (U.S. Patent No. 6,290,990) in view of Seppala et al (U.S. Patent No. 6,011,092). This rejection is respectfully traversed.

Seppala et al does not cure the deficiencies in the disclosure of Grabowski et al. discussed above, and even if it were obvious to combine the teachings of Grabowski et al and Seppala et al, Applicant's claimed invention would not be obtained nor rendered obvious. The Examiner maintains that Grabowski et al differs from the instant claims insofar as the reference does not disclose the compositions comprise semolina in the plasticized matrix. As discussed above, Grabowski et al does not employ water as a

plasticizer for the matrix material and specifically teaches away from its use in producing the product. Even if it were obvious to employ semolina in the product of Grabowski, which it is not, Applicant's claimed products would not be obtained nor rendered obvious.

According to the Examiner, Seppala et al. disclose thermally plasticized compositions comprising starch, the compositions are used to controllably release fertilizers and medicines, the starches include those derived from wheat, and the starch may be prepared from a natural starch by gelatinization, or a starch derivative prepared by oxidation, hydrolysis, cross-linking, cationization, etherification and esterification.

However, Seppala et al is directed to a new melt processible, starch based polymer composition and a process for the preparation thereof. The starch component is compatibilized with the thermoplastic component so as to provide an essentially homogeneous blend. The thermoplastic component used comprises a biodegradable hydroxy acid polyester, which is essentially hydroxy-terminated. A polyester prepolymer is reacted with a diisocyanate, which reaction results in an isocyanate-terminated oligomer, which is capable of reacting with the hydroxyl groups of the starch. See col. 3 lines 5-18.

The polymer compositions according to the Seppala et al invention are "internally plasticized", i.e. the coupling agent between the polyester and the starch seems to achieve chemical bonding of the components. According to Seppala et al, even if the starch component and the polyester would not have reacted chemically with each other, the end product is migration-free, because the molar mass of the polyester is large. Moreover Seppala et al discloses that: "Thus, in the present case no monomeric plasticizer is used which would easily migrate." (Emphasis added.) See col. 4 lines 57-62, and col. 7 lines 37-45. Clearly, Seppala et al does not employ water as a plasticizer for a matrix material as claimed, and combining the teachings of Seppala et al with those of Grabowski et al would not result in a product having water as a plasticizer.

Furthermore, the polymer produced in the Seppala et al process, even if it is made using starch derived from semolina, it is not semolina as claimed. According to Seppala et al the starch employed as a component in making the polymer is substantially destructured

and then reacted or compatibilized with other components to form a polymer, which is different from and has different release properties from semolina. See col. 6 lines 3-11 and 35-62.

The rejection is untenable and reconsideration and withdrawal thereof is respectfully requested.

Claims 82, 85 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grabowski et al. (U.S. Patent No. 6,290,990) in view of Seppala et al (U.S. Patent No. 6,011,092) as in claims 42, 53, 69, 70 and 84 above in further view of Andersch et al (U.S. Patent No. 5,804,208). This rejection is respectfully traversed.

Andersch et al does not cure the deficiencies in the disclosures of Grabowski et al and Seppala et al discussed above, and even if it were obvious to combine the teachings of Grabowski et al, Seppala et al, and Andersch et al, Applicant's claimed invention would not be obtained nor rendered obvious. The Examiner maintains that Grabowski et al. and Seppala et al. differ from the instant claims insofar as they do not disclose the active agent is a microorganism, but Andersch et al disclose granules comprising semolina as a carrier for microorganisms suitable for controlling pests. According to the Examiner, it would have been obvious to use the Andersch et al granules comprising microorganisms as the pesticides used in the combined compositions of Grabowski et al and Seppala et al.

However, according to Andersch et al, the microorganisms are carried on the surface of the semolina carrier particles. See col. 1 lines 4-8, 19-22. It is not seen why one of ordinary skill in the art would take the product of Andersch et al and then encapsulate the product in the matrix material of Grabowski et al and Seppala et al, because doing so would defeat the purpose of Andersch et al of having the microorganisms on the surface of the particles. Furthermore, Grabowski et al teaches mixing all of the components together and melt extruding of the mixture at elevated temperatures, and Seppala et al teaches using conditions which would substantially destructure starch. The processing conditions of Grabowski et al and Seppala et al would destroy the microorganisms of Andersch et al, and

one of ordinary skill in the art would not use the Andersch et al granules comprising microorganisms as the pesticides used in the combined compositions of the Grabowski et al. and Seppala et al references.

Reconsideration and withdrawal of the rejection is respectfully requested.

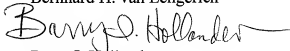
CONCLUSION

In light of the foregoing amendments and remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

The fee for the two additional independent claims is submitted herewith. The U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed necessary or to credit any overpayments to Deposit Account No. 19-0089 (P32853).

Respectfully submitted,

Bernhard H. van Lengerich

A handwritten signature in dark ink, appearing to read "Barry I. Hollander", with a long horizontal flourish extending to the right.

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